REMARKS

In the Office Action dated December 18, 2006, claims 1-95 are pending, claims 1-59 are withdrawn, and claims 60-95 are rejected. Reconsideration is requested, at least for the reasons discussed herein.

The invention set forth in claim 60 is directed to:

> A method for treating a specimen of semen containing sperm cells to increase the relative number of sperm cells of a preferred sex type in a treated specimen to increase the potential for conceiving an offspring of the preferred sex, the method comprising separating the semen into two components comprising a first component having a higher number of sperm of the preferred sex type than sperm of a non preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred sex type, wherein the separating step is performed in a window of time determined by locating a maximum in the curve obtained by plotting percent female cells determined by FISH against percent Koo positive cells, determining the time at which the maximum percent female cells occurs, and beginning the separation step no earlier than about one hour before the time of the maximum percent female cells.

Applicants have discovered that one can significantly increase the relative number of sperm cells of a preferred sex type in a treated specimen to increase the potential for conceiving an offspring of the preferred sex by determining a time when a maximum of the percent female cells is present in a sample of semen and, then, begin the separation step no earlier than about one hour before the time of the maximum percent female cells, where the separation step separates the semen into two components comprising a first component having a higher number of sperm of the preferred sex type than sperm of a non preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred sex type.

None of the cited art teach or suggest the timing of the separation step as claimed herein.

Claims 60, 67, 75, 86 and the claims dependent thereon (61-66, 68-74, 76-85 and 87-95) are rejected under 35 USC 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the claimed invention. The Examiner alleges that it is not described in the specification how one sample to be separated into components can differ in the amount of female vs. male cells over time and how a maximum is determined. Applicants strongly disagree.

As recognized by the Examiner, Applicants show that samples separated at different times, when analyzed by FISH, contain varying numbers of viable male and female cells. By plotting the number of female cells or male cells vs. time at a particular temperature, one can determine a maximum in the number of cells vs. time at a particular temperature. By observing the actual maximum, one can determine the optimum temperature for the methodology being utilized. Figures 2-6 illustrate that a maximum number of cells can be determined by FISH using Koo cells. Thus, Applicants clearly have demonstrated that they were in possession of the claimed subject matter at the time the application was filed.

The Examiner states that Applicants appear to be claiming using the FISH analysis to track when more female cells are present in a single sample. Applicants submit that they have discovered that the FISH analysis can be used to determine a time period during which a maximum of viable female cells are present in a sample, and such window can be further used for separating semen samples into male and female cells.

By separating the semen at such determined time, one can provide a component of semen that has a higher percent of female cells, as taught by the present application.

The Examiner states there is no scientific support for the Applicants' discovery. That is the nature of the discovery. Applicants have provided the support in the specification and figures.

The Examiner states that examples do not support analyzing the percent female cells before the separation step. However, that is not required.

The claimed method is for treating a specimen of semen containing sperm cells to increase the relative number of sperm cells of a preferred sex type in a treated specimen to increase the potential for conceiving an offspring of the preferred sex, and it requires:

> separating the semen into two components comprising a first component having a higher number of sperm of the preferred sex type than sperm of a non preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred sex type.

This method is performed in a window of time after ejaculation:

> wherein the separating step is performed in a window of time determined by locating a maximum in the curve obtained by plotting percent female cells determined by FISH against percent Koo positive cells, determining the time at which the maximum percent female cells occurs, and beginning the separation step no earlier than about one hour before the time of the maximum percent female cells.

It is not seen where any undue experimentation is required to practice the claimed invention.

Claims 60, 61, 63 and 75 are rejected under 35 U.S.C. 102(b) over Sills et al. (American Journal of Reproductive Immunology, vol. 40, 1998; "Sills"). Sills concludes that:

> [t]he expression of H-Y antigen has a slightly higher frequency in human sperm containing the Y-chromosome, but its expression among X-chromosome-bearing sperm also is considerable. Current immunological

techniques relying on this antigen are unlikely to effect sex selection of human sperm.

Thus, Sills ***fails*** to teach or suggest a method for treating a specimen of semen containing sperm cells to increase the relative number of sperm cells of a preferred sex type in a treated specimen to increase the potential for conceiving an offspring of the preferred sex, as claimed herein.

Sills also ***fails*** to teach or suggest a method that includes:

> separating the semen into two components comprising a first component having a higher number of sperm of the preferred sex type than sperm of a non preferred sex type and a second component having a higher number of sperm of the non preferred sex type relative to sperm of the preferred sex type,

as claimed herein.

Further, Sills ***fails*** to teach or suggest a method

> wherein the separating step is performed in a window of time determined by locating a maximum in the curve obtained by plotting percent female cells determined by FISH against percent Koo positive cells, determining the time at which the maximum percent female cells occurs, and beginning the separation step no earlier than about one hour before the time of the maximum percent female cells.

Thus, it is not seen how the presently claimed invention is anticipated by Sills. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Sills.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(b) over Benjamin (US 6153373). Although Benjamin '373 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of

mammalian offspring of either sex. Indeed, Benjamin '373 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '373. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '373.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(a) and (e) over Benjamin (US2003/0068654A1). Although Benjamin '654A1 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. Indeed, Benjamin '654A1 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '654A1. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1.

Claims 60-62, 67-69, 82-83, 86-91 and 93 are rejected under 35 U.S.C. 102(a) and (e) over Benjamin (6489092). Although Benjamin '092 describes a method for increasing the percentage of mammalian offspring of either sex by contacting a sperm sample with an antibody specific to a selected spermatozoa type, Benjamin ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. Indeed, Benjamin '092 does not even suggest that such a window can exist. Present Applicants have discovered the existence of this

window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Benjamin '092. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '092.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. 102(b) over Blecher et al (US2001/0041348 A1; "Blecher"). Although Blecher describes a method for separating semen into male and female determining sperm with antibodies bound to carriers, such as beads, specific for sex-chromosome molecules, Blecher ***fails*** to teach or suggest that a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. Indeed, Blecher does not even suggest that such a window can exist. Present Applicants have discovered the existence of this window and how to use it for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention is anticipated by Blecher. Further, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Sills (AJRI, vol. 40, 1998). The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male vs. female sperm cells in a sample. Applicants agree. However, that is not the presently claimed invention.

The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of

time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Sills, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Sills, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Sills. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Sills, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Blecher or Sills, or any combination of them.

Claims 60-62, 67-69, 75 and 82 are rejected under 35 U.S.C. §103(a) over Zavos et al. (US 4999283; "Zavos") in view of Sills. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Neither Zavos nor Sills, nor their

combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Zavos or Sills, or any combination of them.

Claims 60-62, 67-69, 73 and 74 are rejected under 35 U.S.C. §103(a) over Van den Bovenkamp (US 3687806) in view of Sills. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Neither Van den Bovenkamp nor Sills, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Sills, or any combination of them.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Johnson (Reprod. Fertil. 1995). The Examiner states that it would have been obvious to one of

ordinary skill in the art at the time the invention was made to have used FISH in analyzing the percentage of male vs. female sperm cells in a sample. Applicants agree. However, that is not the presently claimed invention.

The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Johnson, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Johnson, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Johnson. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Johnson, nor their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

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maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Johnson, or any combination of them.

Claims 60-63, 67-70, 75-80, 82-83, 86-91 and 93 are rejected under 35 U.S.C. §103(a) over Benjamin '654A1 or Benjamin '373 or Benjamin '092 in view of Spaulding (US 5021244). The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention to cool the semen after collection. However, embodiments of the presently claimed invention are more than cooling the semen.

The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Not one of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Spaulding, or their combination, teach or suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex.

Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Benjamin '654A1 or Benjamin '373 or Benjamin '092 or Spaulding, or any combination of them.

Claims 60-63, 67-70 and 75 are rejected under 35 U.S.C. §103(a) over Belcher '348A1 in view of Spaulding. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time. Neither Blecher nor Spaulding, nor their combination, teach or

suggest a window of time after ejaculation can be determined for performing the separation to obtain the desired increase in the percentage of mammalian offspring of either sex. The present invention uses FISH with Koo positive cells to determine the time when particular sex type sperm cells are at a maximum and uses that time to provide a window for performing a separation into of the semen sample into male-rich and female-rich components. None of the cited prior art teach or suggest such a window of time.

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Thus, it is not seen how the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Van den Bovenkamp or Spaulding, or any combination of them.

In view of the discussion above, applicant respectfully submits that the pending application is in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

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Respectfully submitted,

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